

APR - 7 1997

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**510(k) Summary of Safety and Effectiveness**

<b>Submitter:</b>		<b>Date of Preparation:</b> December 28, 1996	
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Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
<b>Product Information:</b>			
Trade name: Riwo Drive Generator and Accessories		Model number: 2302, motor handle 8561.121 and various rotary blades and abraders (see section 1: Submitted devices)	
Common name: Drive Generator		Classification name: Instrument, surgical, orthopedic, DC-powered motor and accessory/attachment	
<b>Information on devices to which substantial equivalence is claimed:</b>			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 K871250	1 Intra-articulated arthro power system 2161	1 Richard Wolf M.I.C.	
2	2 Surgical Drive System EP-1	2 Dyonics	
3	3 Shaver System SE 5	3 Stryker	
4	4 Drive System Apex	4 Linvatec	

**1.0 Description**

The RIWO Drive Generator is build to efficiently drive and control different motor handles. The handle functions are controlled by a footswitch.

The Motor Handle is a tubular system with a motor and clamping chuck for driving rotary blades and abraders. A suction pump is connected to the built-in suction tube and the suction stream can be controlled by a valve.

The rotary blades consist of a hollow, fenestrated tube, containing a rotating two-edged cylindrical blade or an abradar that spins within the hollow tube.

## 2.0 Intended Use

The Riwo Drive System is used for arthroscopic procedures in human joints. It is also used for sinus procedures in the nasal cavity.

The Riwo Drive generator with motor handle serves to drive WOLF blades or abraders.

Depending on the indication, different styles of blades are attached to the motor handle. Two basic styles are most common:

1. Blades are for removal of soft tissue and cartilage
2. Abraders for bones and bony structures

The use of the system is reserved to surgeons with special training in the respective procedures.

## 3.0 Technological Characteristics

### Riwo Drive Generator:

- Four user specified, selectable settings for the speed
- continuous digital display of desired and actual speed
- automatic adaptation of speed range and maximal torque (current) for three different motor handles, display of speed range with LED
- acoustic and optical alarm for: overload of motor, incorrect cable connection or interrupted cable
- footswitch to control motion forward, reverse, oscillation (3 changes per second), speed and speed range by the surgeon, automatically stored.

### Motor handle:

- 360° rotation of clamping chuck for various cutting position
- variable suction control with one-hand operation
- watertight housing and cable, for steam sterilization
- lightweight design
- detachable cable
- BF insulation according to IEC601-1

### Rotary Blades and Abraders:

- atraumatic design
- colored coding
- sterile, for single use
- various diameters and tip designs

## 4.0 Substantial Equivalence

The submitted devices are substantially equivalent to existing pre-enactment devices sold by Richard Wolf and 510(k) devices sold by Storz.

**5.0 Performance Data**

The Riwo Drive Generator 2302 with Footswitch 2030.221 and with the Motor handles 8561.121 and 8562.111 were tested according to the specified standards IEC601-1, IEC601-1-2 and UL2601-1. A life-cycle test shows that the function of the motor handle can be guaranteed for more than 200 steam sterilization cycles when using the fractional method.

**6.0 Clinical Tests**

No clinical tests performed.

**7.0 Conclusions Drawn**

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the Instruction manual.

By: Robert L. Casarsa

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Date: Jan 8, 97